IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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#103
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In Re the Application of :)
Jacqueline R. Doyle et al)
)
Serial No. : 09/364,343) Examiner. Mendez, Manuel A.
)
Filed : 07/30/99)
) Art Unit : 3763
For : WOUND IRRIGATION)
AND DEBRIDING SYSTEM)

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February 25, 2004

Federal Express Tracking Number : 837457173957

Assistant Commissioner of Patents
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Sir :

APPEAL BRIEF

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Real Parties In Interest

The real parties in interest herein are the owners of the present application, namely Jacqueline R. Doyle and Kenneth F. Short.

Related Appeals and Interferences

No other appeals or interferences directly affect or will be directly affected by the Board's decision in the present appeal.

Status of Claims

The application as filed contained claims 1 to 8. This appeal concerns the rejected claims 1 to 8.

Status of Amendements

By an Office Action originally dated 02/07/02, having a Restart Date of 08/01/02, all claims (1 – 8) were finally rejected. Responsive to the Final Rejection, an Amendment and Response was filed on 01/30/03. By an Advisory Action on or about 03/03, that Amendment and Response was refused entry. In the interim, an interview with the Examiner was held on 02/26/03, as a result of which Examiner issued an ``Examiner Interview Summary Record``, dated 02/26/03. This Record identified the prior art as U.S. Patent No. 4,752,288, by Hussey, and included specific recommendations to overcome the Hussey reference. An Amendment and Response responsive to the ``Examiner Interview Summary Record`` was filed on 03/26/03. That Amendment and Response was refused entry.

SUMMARY OF THE INVENTION

This invention relates to medical apparatus for the irrigation and debriding of wounds and incisions by means of a device in which a unit dose of sterile (USP) saline solution (120-200 cc, preferred) or a sterile distilled water solution is dispensed for the irrigation and cleansing of a wound or incision. (spec. p.1, lines 1 – 4, and p.2, lines 18-19).

Applicants' claimed invention consists of a one-piece dispenser comprising an irrigation solution, an irrigation solution chamber, a nozzle, a nozzle protective tip with a removable packaging band around it for additional protection during storage and moving and an optional filter. (Figs. 1 and 5.) In one embodiment, the nozzle assembly is screwed onto the solution chamber at point of manufacture, (Figs. 2,3,4.) In another embodiment, the nozzle and solution chamber are molded into one unit during the manufacturing process. (Fig. 6.) In both embodiments, the unit is sterilized at point of manufacture. The nozzles may be straight (Figs. 1,3) or at varying degrees of angles. (Fig. 4) (spec. p3, lines 8 – 9.)The entire device is made of a flexible material, preferably plastic.

The device of the present invention is free standing and can be conveniently placed anywhere in the sterile field being used for this procedure. When ready for use, the packaging band is removed. The protective tip is then removed from the nozzle and irrigation is effected by applying hand pressure to the walls of the solution chamber. The sterile irrigation solution passes from the chamber through the nozzle to the wound area. When solution flow is stopped, the air reentering the chamber may be further protected from contamination by employing the optional filter, which is located between the end of

the nozzle at the inlet into the solution chamber. The filter may be a diaphragm-type valve, e.g., a Mitral filter valve, which is a diaphragm of filter medium that expands under internal pressure to create an orifice and collapses back into place with the release of internal pressure. Another embodiment is a Clapper Filter, which is filter medium assembled to a one-directional clapper valve frame. Both filter types operate on the same basis. When pressure is applied from inside, the filter opens to allow passage of fluid from the chamber through the delivery nozzle and tip to the wound. When inside pressure is released, the returning air to the chamber restores the filter to its original position, thereby allowing the filtration of the returning air into the chamber. This filtration minimizes the contamination of the remaining irrigation solution during necessary interruptions in the irrigation treatment.

Since the entire assembly can be placed in an upright, free standing, position, the nozzle is prevented from possible contact with contaminated areas, allowing for safer interruptions of the wound care procedure. When the irrigation solution is depleted, the empty device may be discarded in its entirety, in any common waste receptacle. No Sharps Hazard Disposal requirements apply to the device of the present invention. (Spec, p. 3, lines 15 – 38.)

ISSUES

The issues are as follows:

1. Claims 1,3,4 and 5 are rejected under 35 U.S.C. 102 (b) as being anticipated by the Hussey U.S. patent No.4,752,288 , hereinafter ``Hussey``.

2. Claim 2 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Hussey in view of the Reddick U.S. patent No.4,894,053, hereinafter ``Reddick``.

3. Claim 6 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Hussey in view of the Rose U.S. patent No.2,135,052, hereinafter ``Rose``.

4. Claim 7 and 8 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hussey in view of the U.S. Wallace, et al patent No.6,066,325, hereinafter ``Wallace at al``.

5. Applicants proposed amendments to the specification of the term ``non-invasive`` has been rejected under 35 U.S.C.132 as introducing new matter.

6. Examiner concludes that the amendment to the preamble of claim 1 of the phrases ``one-piece`` and ``which is disposable in any container`` Do not overcome the 102 (b) rejection.

GROUPING OF CLAIMS

There is only one independent claim, i.e., claim 1. Dependent claims 2-8 stand or fall with claim 1.

ARGUMENT

1. Claims 1,3,4 and 5

Applicants appeal the rejection under 35 U.S.C. 102 (b) as being anticipated by Hussey, as to claims 1,3,4, and 5, for the following reasons:

In Schroeder v. Owens-Corning Fiberglas Corp., 514 F2d 901, 185 USPQ 723 (1975, CA 9 Cal.), the court states "An invention is said to be anticipated only if another invention already known or used is identical in substance ` Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a prior art reference there is no anticipation ´ (citing Walker v. General Motors Corp. (CA9 Cal) 362 Fed2d 56,58,149 USPQ 472,473,474.)"

Hussey describes a tamper –proof closure for an enema unit comprising a bottle and a rectal tip with a break- off tab, which, in turn, consists of a spherical ball mounted on top of the tip so as to completely enclose the circular passage through the tip, in an attempt to prevent any contamination or spillage of the fluid. The ball is removed by twisting it. The tip is coated with a lubricant. A sleeve is slid over the tip and heat- shrunk so as to protect the lubricant on the tip from contamination (Hussey spec. col. 3, lines 1-26). The lubricant is needed precisely because of the nature of an enema. It is inherently intrusive.

The thrust of all of Hussey's claims is, in fact, the tamper-proof closure over a ``container``. (Hussey, cl. 1-8.)

Applicants' claimed invention is a dispenser for wound irrigation and debriding. It does not require lubricating the nozzle as it is not intrusive. In fact, Applicants' nozzle,

as shown in Figs. 1,3,4, and 6 could not safely function as an enema tip. Applicants' tip as claimed and described, is not for rectal insertion but to protect the sterile fluid from contamination. It is not designed as a closure for an enema; it has no break-off tab, no spherical ball. The lubricant coated tip and the closure system patented by Hussey, requiring a break-off tab, a twist-off ball, and a heat-shrunk sleeve is so substantially different from Applicants wound irrigation system as not to anticipate under §102 (b).

Further Hussey's enema unit is in a different art field than Applicants' wound irrigation system. Applicants' invention is concerned not just with sterility of solution, but with rapid delivery and simple disposability without the requirements of Sharps Hazards regulations.

As to claims 3, 4, and 5 Applicants do not assert that these dependent claims are separately patentable species. These variations cannot be evaluated alone but as a further limitation of independent claim 1 on which they rely and with which they merge as dependent claims.

2. Claim 2

Claim 2 has been rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Reddick. This rejection is respectfully traversed for the reasons noted below.

If, as Applicants contend, Hussey does not anticipate Applicant's invention since Hussey does not contain each and every limitation of Applicants' invention, then it

should be immaterial whether Reddick's filters would have been obvious to modify Hussey.

Applicants do not claim as novel per se, the use of a filter in their invention. Rather, dependent claim 2 incorporates all of the elements of independent claim 1, adding the filter as a further limitation. Within this context, Applicants contend that selectively choosing the filters of Reddick's douche apparatus to add to Hussey's closure system for an enema unit does not result in the obviousness of Applicant's invention. Hussey's enema, even with Reddick's filter, would not make it obvious to constitute Applicants' claimed wound irrigation and debriding system. Such a combination would have no utility or meaning for a wound irrigation system.

3. Claim 6

Claim 6 is rejected under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Rose, because Rose uses an angled nozzle. Rose describes and claims a nasal douche , which is inserted "snugly into the nostril". (Rose spec., Col 2, Line 40.) Here, again, Applicants have never claimed that the angle of their nozzle is per se patentable. Dependent claim 6 must be read as a limitation on claims, not as novelty per se. Applicants repeat and reaffirm all of the same arguments against a finding of obviousness over their invention as they did for the previous reference of Reddick in view of Hussey, except that the argument here refers to angled nozzles rather than filters.

4. Claim 7 and 8

Examiner rejects claims 7 and 8 under 35 U.S.C. 103 (a) as unpatentable over Hussey in view of Wallace et al. Hussey does not disclose a dispenser having a sterile solution containing sodium chloride and/or distilled water. Hussey describes and claims a closure system for an enema. Wallace at al describes and claims polymeric compositions and methods. One means of delivering the hydrogel of the Wallace invention is a syringe. (See, for example, Figs. 1, 2A, 3A, and 4.) Applicants do not claim a syringe. A syringe may be appropriate for an enema, but it is deliberately not used for the wound irrigation system described and claimed by Applicants.

Applicants disagree that the enema system of Hussey would be an obvious alternative to Applicants' dispenser, considering the totality of Applicants' wound irrigation and debriding system.

Applicants are not claiming the sterile solutions of dependent claims 7 and 8 as patentable per se. They do assert, however, that the entire invention as claimed, taken in its entirety is patentable, when the dependent claims are read in conjunction with the independent claim 1.

5. As previously noted, Applicants appeal Examiner's decision not to allow amendment of the specification to add the term ``non-invasive``. Although that term is not used in the specification, Applicants' device is clearly non-invasive as shown in the nozzle configuration of Figs. 1,3,4,6; and from the description in the specifications, p.2, lines 33-40.

6. Further in response to Applicants' amendment of 11/16/01, Examiner concluded that Applicants amendment to the preamble of claim 1, adding the phrases ``one-piece`` and ``which is disposable in any container``, did not overcome the 102 (b) rejection.

Referring to In re Larson, 340 F. 2d 965, 144 USP1 347, 349 (CCPA1965), Examiner states that the difference between a one-piece or a multiple design is an obvious design choice.

Applicants agree with Examiner that the difference between a one-piece or a multiple piece design is often an obvious design choice. However, not always.

In Re Hubbell 35 CCPA 782, 164 F2d 700, 76 USPQ105, (1947), the Court stated that while, as a general rule, it is not invention to make in one piece what had previously been made in more that one piece, where the article produced is novel, useful and not anticipated, it should be regarded as involving the element of invention.

This rule of law goes back to at least as far as Kementz v. s. Cottle Co., 148 US 556, 37 L. Ed 558, 13 S CT 719 (1893), in which the U.S. Supreme Court held a collar button with a one-piece head and stem was patentable over a multi-piece collar button.

"There is no per se rule that making something in one piece that was formerly made in two or more pieces renders it obvious. Rather, the Court must look beyond the mere fact of unitary construction to determine what improvement results from the one

piece construction and whether the improvement or construction itself was obvious from the prior art." Mooney v. Brunswick Corp. 489 F Supp 544, 206 USPQ 121 (1980, ED Wis). Note also Re Larson, 52 CCPA 930, 340 F2d 965, 144 USPQ 347 (1965).

Prior to Applicants' invention, wound irrigation systems came in separately packaged parts as explained in Applicants' application. For lack of a better solution, this is the type of system presently in use. Separate packaging of each element is not just a simple design choice. It is an inherent cause of potential contamination, which is a substantive problem in a hospital environment.

Applicants' invention which is one piece has solved the problem of contamination inherent in prior art systems (multi-parts) as explained in the specifications. Applicants' invention is also more efficient and less costly because it is not multi-part construction.

The phrase "which is disposable in any containers" also is an important and substantive characteristic of the invention because of its structure, i.e., it eliminates the need for a syringe and, hence, the need for Sharps Hazard Disposal systems. Therefore, it allows disposal in any container, and is not confined to the costly, rarer, and regulated Sharps Hazard Disposal systems.

7. Present wound irrigation and debriding systems comprise independently packaged items, i.e. a sealed sterilized bottle of saline solution, a sterile bowl, and a sterile syringe. All items are opened and placed onto a sterile field; the bottle of saline solution is unsealed and poured into the now-opened bowl and then drawn up into the syringe. The

system is now ready to irrigate the wound or incision. Major drawbacks to the current system are as follows: First is the precious time that is lost, especially in an emergency, unpacking and assembling this system for use. Second, and most critical, is the immediate exposure of all of these items to local contaminates. Once the seal on the bottle of saline solution is broken, the solution is now subject to contamination. This is even more so when the solution is poured into the now- exposed bowl. The already exposed solution is then drawn into the sterile syringe. The entire wound irrigation system is thus potentially contaminated. The sterile field on which this operation is performed is a sterilized, prepackaged sheet of paper that is removed from its protective packaging, unfolded and placed upon whatever surface the attending person is using for the procedure. If this surface becomes wet, it is then considered contaminated and rendered ineffective. The surface could be in a hospital operating or emergency room, a school nurse's office, an accident site, or a military field hospital. All are areas that could easily contaminate the exposed, wound irrigation system. An example of this contamination could be Staff Infection, which is easily spread, especially in hospital environments. Further, because a syringe is used, it must be disposed of, after use, into a Sharps Hazards container, at considerable cost to the facility. (spec. p.1, lines 5 – 25;p.2, lines 5-6.)

Applicants invention fulfills a long-sought need. To this effect, Applicants have filed with Examiner the affidavits of Kristn Lavoie, RN, CWON, and Tomas D. Divinagracia, MD, General Surgeon.

Applicant's invention addresses the needs of the medical art dealing with wound irrigation and debriding, particularly under emergency conditions, where time is of the essence, sterility of the unit is essential, and disposability and economy is important.

CONCLUSION

For the foregoing reasons, the examiners rejection of claims 1 – 8 is unwarranted, and reversal thereof is respectfully requested.

The filing fee for the brief in the amount of Dollars 165.00 is filed herewith. Also filed herewith is a request for extension of time, along with the requisite fee.

Respectfully submitted,

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APPENDIX

(THE CLAIMS)

1. A one-piece sterile non-invasive dispenser for the rapid irrigation and debriding of wounds and incisions, which is disposable in any container, comprising:

a flexible chamber having an internal volume containing a sterile solution, said chamber having an orifice at one end thereof;

a non-invasive nozzle having a first opening at one end and a second opening at the other end thereof, wherein said first opening is affixed to said orifice of said chamber; and said second opening dispenses said solution;

a protective tip affixed to said second opening of said nozzle, thereby maintaining said solution in a sterile state;

and a removable packaging band around said protective tip.

2. The dispenser of claim 1 wherein said nozzle contains a filter at said first opening.

3. The dispenser of claim 1 wherein said nozzle has a screw-on cap affixing said first opening to said orifice of said chamber.

4. The dispenser of claim 1 wherein said nozzle is molded to said chamber.

5. The dispenser of claim 1 wherein said nozzle is angled.

6. The dispenser of claim 1 wherein said nozzle is straight.

7. The dispenser of claim 1 wherein said sterile solution contains 0.9 percent USP sodium chloride.

8. The dispenser of claim 1 wherein the said sterile solution contains 0.9 percent distilled water.

CERTIFICATE OF MAILING

The undersigned hereby certifies that the document attached hereto has been deposited with the Federal Express No. 837457 17 3957 on February 25, 2004 in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231

Dated: February 25, 2004

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